510(k) Summary

Device Trade Name: Dymaxeon Spine System

NOV 5 2012

Manufacturer:
B2B Spine PTY LTD
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Baulkham Hills NSW 2153 AUSTRALIA

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Date Prepared: June 15, 2012

Classifications: 21 CFR 888.3070: Pedicle screw spinal system

Class: III

Product Codes: NKB, MNI, MNH

Indications for Use:
The Dymaxeon Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1 – S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Device Description:
The Dymaxeon Spine System is a posterior pedicle screw system manufactured from titanium alloy (Ti6Al4V ELI per ASTM F136) designed for temporary stabilization of the spine during the development of spinal fusion. The Dymaxeon Spine System is comprised of polyaxial pedicle screws, reduction screws, and rods. The Dymaxeon Spine System can be used for single or multiple level fixations. The pedicle screws are available in various lengths and diameters.

Predicate Devices:
Comparative information presented in the 510(k) supports the substantial equivalence of the Dymaxeon Spine System to the following predicate devices: Corelink, LLC Tiger™ Spine System (K110321, K113058), DePuy Moss Miami (K103490, etc), Synthes Universal Reduction Screw (K120571, etc), and Scient'x ISOBAR (K990118, K013444).

Substantial Equivalence:
The components of the Dymaxeon Spine System are substantially equivalent to the identified predicates with respect to its indications for use, geometry, available sizes, materials, methods of fixation and performance.

Preclinical Testing:
The non-clinical tests performed by the company include static compression bending, static torsion, and dynamic compression bending testing per ASTM F1717 of the Dymaxeon Spine System. The results of the performed tests demonstrate that the Dymaxeon Spine System is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 5, 2012

B2B Spine Pty, Limited
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Justin Eggleton
Director, Spine Regulatory Affairs
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K121786
Trade/Device Name: Dymaxeon Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: September 26, 2012
Received: September 27, 2012

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K121786

Device Name: Dymaxeon Spine System

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Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121786